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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,967	08/24/2000	Wu Yang	393 A US	3909

7590

03/15/2002

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EXAMINER

KIFLE, BRUCK

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 03/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/645,967

Applicant(s)

Yang et al.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above, claim(s) 42-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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Applicant's amendments and remarks filed 1/2/2002 have been received and reviewed. Claims 1-77 are still pending in this application.

***Election/Restriction***

Applicant's election with traverse of group I is acknowledged. The traversal is on the ground that group II covers the use of the claimed compounds in multimerizing proteins. This is not found persuasive because group II, in fact, is drawn to a method for multimerizing chimeric proteins in cells which raises different issues of patentability and requires separate searches.

Note, claims 1-41 are under consideration, claims 42-77 are withdrawn. Applicants arguments regarding claims within elected group I, claims 1-41, is not on point because these claims are under consideration. Claims 42-45 are drawn to a method for epimerizing the hydroxy group of an aldol moiety in any compound.

Compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept.

***Claim Rejections - 35 USC § 112***

Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In the definitions of R<sup>28</sup> and R<sup>43</sup>, the phrase "substituted or unsubstituted aliphatic or acyl moiety" is indefinite. Applicants point to page 30, line 34-page 35, line 13 to indicate the definitions of these terms. However, mere examples have been stated in the specification and,

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thus, the metes and bounds are not known. The term “acyl” is not defined and one cannot say whether acyl groups derived from sulfonic acid, phosphoric acid, arsenic acid, etc. are all intended or whether only the carboxylic acid acyl groups are intended (alkanoyl). Applicants did not say or show how any acyl group would work. Also, it is still unclear which substituents are permitted and which ones are not as the specification recites only a few examples. The same problems are also still present in the definitions of  $R^A$  and  $R^B$ .

ii) In the definitions of  $R^A$  and  $R^B$ , the groups heteroaliphatic, aryl and heteroaryl are still not clear. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. One cannot say which atoms are present, how many of each are intended or how many rings are present. The term “heteroaliphatic” is not normal nomenclature.

iii) The metes and bounds of the “pharmaceutically acceptable derivative” is still not known. One skilled in the art cannot say when a compound is and no longer is a pharmaceutically acceptable derivative. Is, for example, a pyrano group a pharmaceutically acceptable derivative or is it not? Such a group could be derived from formula I as could thousands more fragments.

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Fed. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

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***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-41 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Grinfield et al. (WO 98/09972). The reference teaches a group of rapamycin derivatives with unnatural stereochemistry. Applicants argue that the reference does not disclose or suggest epimerization of the hydroxyl group at position 28 except in combination with specific other changes in the cyclohexyl moiety. Applicants are referring to the compound of formula I of the reference wherein Y is a and X has the same geometrical isomerism as the methoxy group as opposed to the different spatial arrangement of the instant compound. However, it has been well established that a compound which is isomeric with a compound of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. (In re Norris (CCPA 1950) 179 F2d 970, 84 USPQ 458). Similarly, an optically active isomer is unpatentable over a prior art racemate or optical isomer of opposite rotation in the absence of unexpected or unobvious beneficial properties. In re Adamson et al. (CCPA 1960) 275 F2d 952, 125 USPQ 233.

Therefore, in the absence of a showing that the instant compounds demonstrate unexpected and unobvious results over the prior art compounds, the claims are deemed obvious over Grinfield et al.. Applicants must prove that their compounds possess a property that the prior art compounds do not possess, not is not disclosed to possess. In re Dillon (16 USPQ 1897)

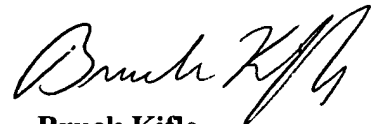
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states "the discovery that a claimed composition possesses a property not disclosed for the prior art subject matter does not by itself defeat a prima facie case."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

March 14, 2002

A handwritten signature in black ink, appearing to read "Bruck Kifle", with a stylized flourish at the end.

**Bruck Kifle**  
**Primary Examiner**  
**Art Unit 1624**